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ELI LILLY AND COMPANY

By Hinda M. Durbin

Date May 24, 2002

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Mark Laurence Brader) Confirm. No.:
Serial No. : 09/980,962) 3515
Filed : June 15, 2000) Group Art Unit:
For : PROTAMINE-FREE INSOLUBLE) 1614
ACYLATED INSULIN COMPOSITIONS)
Docket No. : X-12785)

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Arlington, VA 22202

Sir:

As a means of complying with the duty of disclosure, Applicant submits an "Information Disclosure Citation In An Application" on a Form PTO-1449 (modified) and provides a copy of each of the listed documents for consideration by the Examiner.

Since this Statement is being filed in accordance with 37 C.F.R. 1.97(b), Applicant submits that no additional fee is required.

(1) The pending claims for U.S. Application No. 09/491,253, filed January 26, 2000, entitled "Monodisperse Hexameric Acylated Insulin Analog Formulation." Application No. 09/491,253 is listed on the Form PTO-1449 as document CS.

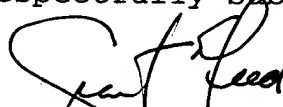
(2) The pending claims for U.S. Application No. 09/958,536, which is the U.S. National Phase Of International Application No. PCT/US00/08723, filed April 13, 2000, entitled

"Insulin Crystals For Pulmonary Administration." The international application published as WO 00/64940, which is listed on the Form PTO-149 as document BR.

(3) The pending claims for U.S. Application No. 10/018,377, which is the U.S. National Phase Of International Application No. PCT/US00/15026, filed June 12, 2000, entitled "Insulin Crystals For Pulmonary Administration." The international application published as WO 00/00674, which is listed on the Form PTO-149 as document BS.

Applicants request consideration of this information. Applicants also request that the Examiner indicate his or her consideration of this information by initialing and signing the Form PTO-1449, and returning a copy of same to the undersigned.

Respectfully submitted,



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May 24, 2002

FORM PTO 1449 (modified)	Atty. Docket No. X-12785	Serial No 09/980,962
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicant(s) Mark Laurence Brader	
	Filing Date June 15, 2000	Group 1614

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Sub-class	Filing Date If Appropriate
	AA	3,864,325	Feb. 4, 1975	Smyth	260	112.7	Nov. 13, 1972
	AB	3,907,763	Sep. 23, 1975	Brandenberg, et al.	260	112.7	Feb. 16, 1973
	AC	3,950,517	Apr. 13, 1976	Lindsay, et al.	424	178	Dec. 6, 1974
	AD	4,701,440	Oct. 20, 1987	Grau	514	3	Jun. 06, 1986
	AE	5,506,203	Apr. 09, 1996	Backstrom, et al.	514	4	Jun. 23, 1994
	AF	5,658,878	Aug. 19, 1997	Backstrom, et al.	514	3	Jun. 6, 1995
	AG	5,693,609	Dec. 02, 1997	Baker, et al.	514	3	Nov. 17, 1994
	AH	5,700,904	Dec. 23, 1997	Baker, et al.	530	305	Jun. 7, 1995
	AI	5,898,028	Apr. 27, 1999	Jensen, et al.	514	4	Mar. 20, 1998
	AJ	5,922,675	Jul. 13, 1999	Baker, et al.	514	4	Nov. 26, 1997
	AK	6,051,551	Apr. 18, 2000	Hughes, et al.	514	3	Oct. 29, 1998
	AL	6,268,335	Jul. 31, 2001	Brader	514	3	Oct. 22, 1998
	AM	6,310,038	Oct. 30, 2001	Havelund	514	4	Mar. 20, 1998
	AN	6,335,316	Jan. 1, 2002	Hughes, et al.	514	3	Mar. 10, 2000
	AO	2001/0039260	Nov. 8, 2001	Havelund	514	4	Apr. 17, 2001
	AP	2001/0041786	Nov. 15, 2001	Brader, et al.	530	300	Jun. 7, 1995
	AQ	2,799,622	Jul. 16, 1957	Schlichtkrull, et al.	167	75	Nov. 12, 1954
	AR	2,819,999	Jan. 14, 1958	Schlichtkrull, et al.	167	75	Nov. 12, 1954
	AS	5,028,587	Jul. 2, 1991	Dorschug, et al.	514	3	May 20, 1988

EXAMINER

DATE CONSIDERED

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	Filing Date June 15, 2000	Group 1614

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FOREIGN PATENT DOCUMENTS								
		Document Number	Date	Country	Class	Sub-class	Translation	
							yes	no
	BA	EP 0646379	04May95	EP				
	BB	EP 0911035	28Apr99	EP				
	BC	EP 0919242	02Jun99	EP				
	BD	EP 0951910	27Oct99	EP				
	BE	WO 95/07931	23Mar95	WIPO				
	BF	WO 95/24183	14Sep95	WIPO				
	BG	WO 96/32149	17Oct96	WIPO				
	BH	WO 98/31346	23Jul98	WIPO				
	BI	WO 98/33480	06Aug98	WIPO				
	BJ	WO 98/42367	01Oct98	WIPO				
	BK	WO 98/42368	01Oct98	WIPO				
	BL	WO 98/42749	01Oct98	WIPO				
	BM	WO 99/21573	06May99	WIPO				
	BN	WO 99/21578	06May99	WIPO				
	BO	WO 99/22754	14May99	WIPO				
	BP	WO 99/32116	01Jul99	WIPO				
	BQ	WO 00/43034	27Jul00	WIPO				
	BR	WO 00/64940	02Nov00	WIPO				
	BS	WO 01/00674	04Jan01	WIPO				
	BT	WO 01/00675	04Jan01	WIPO				

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INFORMATION DISCLOSURE CITATION IN AN APPLICATION		Applicant(s) Mark Laurence Brader	
		Filing Date June 15, 2000	Group 1614
<div style="text-align: center;">OTHER DOCUMENTS</div>			
CA		Brange, Jens, "Galenics of Insulin", Novo Research Institute, pp. 103, Springer-Verlag, Berlin, Germany 1987.	
CB		Byron, P. R. and Patton, J. S., "Drug Delivery via the Respiratory Tract", <i>J. Aerosol Medicine</i> , 7(1):49-75, Mary Ann Liebert, Inc., 1994.	
CC		Galloway, et al., "The Clinical Use of Insulin and the Complications of Insulin Therapy", in: <i>Diabetes Mellitus: Theory and Practice</i> , pp. 519-538, Medical Examination Publishing Co., Inc., New Hyde Park, NY, 1983.	
CD		Galloway, J., "Insulin Treatment for the Early 80s: Facts and Questions About Old and New Insulins and Their Usage", <i>Diabetes Care</i> 3(5):615-622, American Diabetes Assoc., Inc., 1980.	
CE		Galloway, J.A., et al., "Improving Insulin Therapy: Achievements and Challenges", <i>Horm. Metab. Res.</i> 26:591-598, Georg Thieme Verlag Stuttgart, New York, 1994.	
CF		Edwards, et al., "Recent advances in pulmonary drug delivery using large, porous inhaled particles", <i>J. Appl. Physiol.</i> 84(2):379-385, the American Physiological Society, 1998.	
CG		Edwards, D. A., et al., "Large Porous Particles for Pulmonary Drug Delivery", <i>Science</i> , 276:1868-1871, American Assos. Advancement Science, 1997.	
CH		Laube, et al., "Proving the Efficacy of Insulin Delivered Through the Lungs as an Aerosol", <i>J. Biopharm. Sci.</i> 3(1/2):163-169, St. Cosmas-Damian Scientific, 1992.	
CI		Low, B., et al., "Insulin/proinsulin, a new crystalline complex", <i>Nature</i> 248:339-340, Macmillan Publishers, Ltd., 1974	
CJ		Niven, R., "Delivery of Biotherapeutics by Inhalation Aerosol", <i>Crit. Rev. in Therapeutic Drug Carrier Systems</i> , 12(2&3):151-231, Begell House, Inc., 1995.	
CK		Ottesen, et al., "The potential immunogenicity of human insulin and insulin analogues evaluated in a transgenic mouse model", <i>Diabetologia</i> 37:1178-1185, Springer-Verlag, 1994.	
CL		Patton, J., Bukar, J., and Najarajan, S., "Inhaled insulin", <i>Adv. Drug Delivery Rev.</i> , 35:235-247, Elsevier Science, 1999.	
CM		Patton, J. S. and Platz, R. M., "Aerosol Insulin- A Brief Review", <i>Respiratory Drug Delivery IV</i> , pages 65-74, Interpharm Press, 1994.	
CN		Radziuk, J., et al., "Basal activity profiles of NPH and [Ne-palmitoyl Lys (B29)] human insulins in subjects with IDDM", <i>Diabetologia</i> 41:116-120, Springer-Verlag, 1998.	
CO		Richards, Jane P., et al., "Preparation of a Microcrystalline Suspension Formulation of LysB28ProB29-Human Insulin with Ultralente Properties", <i>Journal of Pharmaceutical Sciences</i> , 88(9):861-867, American Chemical Society and American Pharmaceutical Association, September 1999.	
CP		Steiner, D.F., "Cocrystallization of Proinsulin and Insulin", <i>Nature</i> 243:528-530, 1973.	
CQ		Vanbever, Rita, et al., "Sustained Release of Insulin From Insoluble Inhaled Particles", <i>Drug Development Research</i> 48:178-185, Wiley-Liss, Inc., 1999.	
CR		Whittingham, J. L., et al., "Crystal Structure of a Prolonged-Acting Insulin with Albumin-binding Properties", <i>Biochemistry</i> 36(10):2826-2831, American Chemical Society, 1997.	
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FORM PTO 1449 (modified)			Atty. Docket No. X-12785	Serial No 09/980,962
INFORMATION DISCLOSURE CITATION IN AN APPLICATION			Applicant(s) Mark Laurence Brader	
			Filing Date June 15, 2000	Group 1614
	CS		U.S. Patent Application Serial No. 09/491,253.	
	CT		Pending claims for U.S. Application 09/491,253 (11 pages).	
	CU		Pending claims for U.S. Application 10/018,377 (4 pages).	
	CV		Pending claims for U.S. Application 09/958,536 (6 pages).	
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